

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

UNITED STATES OF AMERICA,)	
<i>ex rel.</i> SALLYJO ROBINS, KATHLEEN)	
DUNLAP, GERMANO LIMA, and ROBERTO)	
RABASSA,)	Civil Action No.1:10-CV-12256-DPW
)	
Plaintiffs–Relators,)	
)	
LINCARE INC. and)	
LINCARE HOLDINGS, INC.,)	
)	
Defendants.)	
_____)	

**STATEMENT OF INTEREST OF THE UNITED STATES IN RESPONSE TO
DEFENDANTS’ MOTION FOR SUMMARY JUDGMENT**

The United States of America submits this Statement of Interest pursuant to 28 U.S.C. § 517, to respond to certain arguments made by Defendants Lincare Inc. and Lincare Holdings Inc. (“Defendants” or “Lincare”) in their Motion for Summary Judgment [Doc. 149]. Although the United States declined to intervene in this action on September 27, 2013 [Doc. 41], the United States remains the real party in interest in this case. *See United States ex rel. Hyatt v. Northrop Corp.*, 91 F.3d 1211, 1214 (9th Cir. 1996). In addition, because the False Claims Act (“FCA”), 31 U.S.C. §§ 3729-3733, is the primary tool used by the United States to prosecute fraud on the government, the United States has a substantial interest in the development of the law in this area and in the correct application of that law in this, and similar, cases. The United States has an especially strong interest in the proper application of the FCA to health care fraud claims (in this case alleged fraud related to oxygen equipment) where fraud could result in significant losses to the Medicare Trust Fund.

While Defendants have moved for summary judgment in this case on several grounds, the United States will focus its Statement of Interest on the single issue of the use of statistical sampling to support liability in FCA cases. For the reasons stated herein, the United States maintains that the Defendants misstate the applicable law on this issue by arguing that Relators cannot use statistical evidence to support FCA liability.

I. PROCEDURAL HISTORY

On March 20, 2014, Relators filed their Second Amended Complaint (“SAC”) which is the subject of Defendants’ Motion for Summary Judgment. In their Complaint, Relators alleged that Lincare engaged in a nationwide scheme to bill the government for portable oxygen tanks that were not medically necessary and therefore not reimbursable by Medicare. Relators alleged that Defendants primarily engaged in this scheme after changes to Medicare reimbursement regulations for oxygen services and supplies that took effect on January 1, 2009.¹ Relators further alleged that Lincare submitted claims for oxygen equipment (stationary concentrators) despite knowing that patients were or should be “inactive” and not eligible to receive the stationary concentrators. Relators also alleged that Lincare failed to prevent this billing fraud. Finally, Relators alleged that Lincare provided kickbacks to referral sources and improperly waived patient co-payments and deductibles. On September 27, 2013, the United States declined to intervene in this case and the Relators proceeded with the litigation [Doc. 41].

¹ Effective January 1, 2009, the Centers for Medicare and Medicaid Services (“CMS”) changed the relevant reimbursement regulations by “capping” a patient’s oxygen concentrator rental benefits at 36 months. 42 CFR §§ 414.226(a) & (f). Pursuant to the regulations, this “capped period” lasted from months 37 through 60, which CMS considered the “reasonable useful life” of a concentrator. *Id.* After 60 months, if a patient chose to get a new concentrator, a new “uncapped” 36-month rental period would begin. Prior to 2009, CMS reimbursed DME suppliers providing concentrators through a rental payment for each month the concentrator was in the Medicare beneficiary’s home.

II. ARGUMENT

In their Memorandum in Support of Defendants’ Motion for Summary Judgment, the Defendants misstate the law when they argue that Relators cannot survive summary judgment by using statistical inference to support FCA liability [Doc. 149 pages 18-19]. As discussed *supra*, many courts have recognized that properly validated sampling is a reliable and necessary tool for the effective prosecution of fraud actions involving numerous individual claims.

In its Statement of Interest, the United States is not opining on the substance or reliability of Relators’ expert Dr. Mary Beth Landrum or on the validity of Relators’ sample. The United States takes no position on whether Dr. Landrum’s testimony is admissible or whether her expert reports or opinions have merit. Rather, the United States focuses its Statement of Interest squarely on the issue of the use of statistical sampling to support liability in FCA cases.

A. Description of Sampling and Extrapolation.

Sampling is a common, mathematically proven technique by which estimates of a characteristic of a population can be made based on a sample of that population. *See Mich. Dep’t of Educ. v. U.S. Dep’t of Educ.*, 875 F.2d 1196, 1205 (6th Cir. 1989) (“mathematical and statistical methods are well recognized as reliable and acceptable evidence in determining adjudicative facts”) (quoting *State of Georgia v. Califano*, 446 F. Supp. 404, 409 (N.D. Ga. 1977)); *Mass. Mut. Life Ins. Co. v. Res. Funding Co.*, 989 F. Supp. 2d 165, 172 (D. Mass. 2013); *In re Countrywide Fin. Corp. Sec. Litig.*, 984 F. Supp. 2d 1021, 1037 (C.D. Cal. 2013) (“the purpose of using a sample is to extrapolate results from a small sample to a large population”).

B. Sampling is an Established Method of Proof in Complex Litigation.

Statistical sampling and extrapolation have been widely accepted by federal courts and used in various types of litigation. Courts have approved of the use of statistical sampling and

extrapolation where an individualized claim-by-claim-review of the elements in a case would be unfeasible or extremely costly and where the challenging party is afforded an opportunity to rebut the results. The Supreme Court in *Tyson Foods, Inc. v. Bouaphakeo*, 136 S. Ct 1036, 1046 (2016), held that “representative or statistical samples, like all evidence, is a means to establish or defend against liability,” and “categorical exclusion of such evidence is improper.” *Id.* at 1046. The First Circuit in *United States v. Lahey Clinic Hosp., Inc.* 399 F.3d 1, 18 n.19 (1st Cir. 2005), noted that “sampling of similar claims and extrapolation from the sample is a recognized method of proof.” Further, the Ninth Circuit also held in *Jimenez v. Allstate Ins. Co.*, 765 F.3d 1161 (9th Cir. 2014), that “statistical sampling and representative testimony are acceptable ways to determine liability.” *Id.* at 1167.

In fact, the majority of FCA decisions that have addressed sampling and extrapolation in have approved their use. *See Mich. Dep’t of Educ.*, 875 F.2d at 1205 (6th Cir. 1989); *United States v. Cabrera-Diaz*, 106 F. Supp. 2d 234 (D.P.R. 2000) (upholding use of statistical sampling in FCA case); *United States v. Fadul*, 2013 WL 781614 (D. Md. Feb. 28, 2013) (granting government motion for summary judgment as to damages in FCA case based upon statistical sampling and extrapolation); *Yorktown Med. La., Inc. v. Perales*, 948 F.2d 84, 89-90 (2d Cir. 1991) (approving the use of sampling and statistical evidence to determine Medicaid overpayment); *Ill. Physicians Union v. Miller*, 675 F.2d 151, 155 (7th Cir. 1982) (approving use of statistical samples in Medicaid reimbursement findings); *Blue Cross & Blue Shield of N.J. v. Phillip Morris, Inc.*, 113 F. Supp. 2d 345, 372-75 (E.D.N.Y. 2000) (in RICO case, stating that “[t]he use of statistical evidence and methods in the American justice system to establish liability and damages is appropriate”).

C. Additionally, Statistical Sampling and Extrapolation is a Widely-Accepted Method for Determining Overpayments in Government Benefits Programs.

The use of statistical sampling and extrapolation for determining overpayments in government benefits programs, including Medicare and Medicaid, is both longstanding and commonplace. The Sixth Circuit upheld its use in *Mich. Dep't of Educ. v. U.S. Dep't of Educ.*, 875 F.2d 1196 (6th Cir. 1989), involving an educational grant. In *Michigan*, the United States Department of Education determined that Michigan had misspent funds under a Rehabilitation Act grant. *Id.* at 1198. Federal auditors reviewed 259 sample expenditures, determined that funds were misspent in 13 of the samples, and then projected the total overpayment by extrapolating the results to all 66,368 expenditure authorizations. *Id.* at 1199. The state challenged the use of extrapolation to determine an overall payment amount. The Sixth Circuit rejected the challenge and concluded that sampling was permissible. *Id.* at 1206. Quoting *Califano*, 446 F. Supp. at 409, the court explained that “mathematical and statistical methods are well recognized as reliable and acceptable evidence in determining adjudicative facts.” *Id.* at 1205. The Sixth Circuit recognized that a claim-by-claim review “of the thousands of cases comprising the universe of cases would be impossible.” *Id.* at 1206.

Likewise, statistical sampling in Medicare and Medicaid overpayment cases has been consistently upheld by the courts as a valid means by which the Department of Health and Human Services may determine the amount of overpayment in cases of fraud and abuse by health care providers. *See, e.g., Miniuet v. Sebelius*, 2012 WL 2930746, at *6 (S.D. Fla. July 18, 2012) (“it is undisputed that the Secretary [of Health and Human Services] may utilize statistical extrapolation to determine the amount of overpayment”); *Mile High Therapy v. Bowen*, 735 F. Supp. 984 (D. Colo. 1988) (rejecting speech and physical therapy provider’s challenge to HHS’

use of sampling in Medicare overpayment case); *see also Ratanasen v. State of Cal., Dep't of Health Servs.*, 11 F.3d 1467, 1471 (9th Cir. 1993) (joining other circuits in “approving the use of sampling and extrapolation as part of [Medicare] audits . . . provided the aggrieved party has an opportunity to rebut such evidence”); *Ill. Physicians Union v. Miller*, 675 F.2d 151, 155 (7th Cir. 1982) (rejecting the defendants’ arguments that sampling and extrapolation are improper *per se* and holding that “[t]he use of statistical samples to audit claims and arrive at a rebuttable initial decision was reasonable where the number of claims rendered a claim-by-claim review a practical impossibility”); *Chaves County Home Health Serv. v. Sullivan*, 931 F.2d 914, 919 (D.C. Cir. 1991) (observing that statistical sampling has been allowed in a wide range of contexts “to determine whether there has been a pattern of overpayments spanning a large number of claims where case-by-case review would be too costly”); *Yorktown Med. Lab., Inc. v. Perales*, 948 F.2d 84, 89-90 (2d Cir. 1991 (upholding use of sampling to calculate Medicaid overpayment)); *Balko & Assocs. v. Sec’y*, 555 Fed. App’x 188, 2014 WL 542262 (3d Cir. Feb. 12, 2014) (upholding use of extrapolation in review of Medicare overpayments).

Finally, in *Ratanasen*, the Ninth Circuit rejected a doctor’s argument that statistical sampling prevented him from a claim-by-claim defense. The court explained:

The use of statistical samples was not improper. Projection of the nature of a large population through review of a relatively small number of its components has been recognized as a valid audit technique and approved by federal in cases arising under Title IV of the Social Security Act. Moreover, mathematical and statistical methods are well recognized as reliable and acceptable evidence in determining adjudicative facts.

Ratanasen, 11 F.3d at 1470 (quoting *Califano*, 446 F. Supp. at 409). Thus, sampling is a long-established and well-accepted technique in Medicare and Medicaid overpayment and fraud cases.

D. Courts Have Approved of the Use of Statistical Sampling in FCA Cases.

Courts that have considered the use of sampling evidence have overwhelmingly allowed its admission in FCA cases. *See Cretney-Tsosie v. Creekside Hospice II, LLC*, 2016 WL 1257867, at *6 (D. Nev. Mar. 30, 2016); *United States ex rel. Guardiola v. Renown Health*, 2015 WL 5123375, at *1 (D. Nev. Sept. 1, 2015); *United States ex rel. Ruckh v. Genoa Healthcare, LLC*, 2015 WL 1926417, at *3–4 (M.D. Fla. Apr. 28, 2015); *United States v. Robinson*, 2015 WL 1479396, at *11 (E.D. Ky. Mar. 31, 2015); *United States v. AseraCare, Inc.*, 2014 WL 6879254, at *10 (N.D. Ala. Dec. 4, 2014); *United States ex rel. Martin v. Life Care Ctrs. of Am., Inc.*, 114 F. Supp. 3d 549, 567 (E.D. Tenn. 2014). Indeed, to hold otherwise in a complex health care fraud case involving thousands of claims, where a claim-by-claim review would be impossible, would effectively give health care providers a *carte blanche* “license-to-steal” from Medicare. *See Yorktown Med. Lab., Inc. v. Perales*, 948 F.2d 84, 90 (2d Cir. 1991) (holding, in administrative overpayment case, that to preclude agency from using statistical sampling would “hamstring” efforts to eliminate fraud).

In *United States ex rel. Loughren v. Unumprovident*, 604 F. Supp. 2d 259 (D. Mass. 2009), the relator alleged that the defendant insurance company caused its insureds to file disability applications with the Social Security Administration that falsely stated that the claimants were unable to work. *Id.* at 260. There were 468,641 applications at issue. *Id.* at 263. The relator sought to introduce expert testimony regarding the use of “statistical techniques to extrapolate the number of false claims within a sample of claims to an estimation of the total number of false claims filed.” *Id.* at 260. After a lengthy and technical analysis of the proposed expert’s statistical methods, the court rejected the relator’s request based on its determination that the sampling methodology was flawed. *Id.* at 269. The court concluded, however, that

“extrapolation is a reasonable method for determining the number of false claims so long as the statistical methodology is appropriate.” *Id.* at 261 (citations omitted). The court explained that “[g]iven the enormous number of claims and the significant time and resources it would take to determine if a single claim were false, the plaintiff understandably deemed it impractical to examine each and every one, and so turned to statistical sampling and extrapolation.” *Id.* at 260.

In *United States v. Fadul*, 2013 WL 781614, at *14 (D. Md. Feb. 28, 2013), the court similarly approved of statistical sampling in an FCA health care fraud case. In finding that statistical extrapolation represented the “soundest measure of damages in the case,” the court explained that “[c]ourts have routinely endorsed sampling and extrapolation as a viable method of proving damages in cases involving Medicare and Medicaid overpayments where a claim-by-claim review is not practical.” *Id.*

In *United States v. Rogan*, 517 F.3d 449 (7th Cir. 2008), the defendant appealed a judgment against him under the False Claims Act for submitting claims to Medicare in violation of the Stark and Anti-Kickback Acts. The defendant contested the use of statistical sampling, but the Seventh Circuit rejected “the argument that the district judge had to address each of the 1,812 claim forms” at issue and held that “[s]tatistical analysis should suffice.” *Id.* at 453.

E. Statistical Sampling is Appropriate, and Has Been Accepted by the Courts, Even Where Each Patient or Claim Involves Unique Characteristics.

Lincare argues that sampling is inappropriate in an FCA case involving patient-specific information [Doc 149 at 18]. Specifically, Lincare argues that because each patient is unique, and because the care of each patient was influenced by the subjective medical judgment of the treating physician, statistical sampling and extrapolation cannot capture all of these variables. *Id.* Lincare’s argument lacks merit because statistical extrapolation is routinely used in the medical

necessity context.

For example, in *Creekside Hospice*, the government alleged that the defendants submitted false claims for hospice services provided to patients who were not terminally ill and were therefore clinically ineligible to receive them. 2016 WL 1257867, at *2–3.² The district court allowed the United States to rely “upon the extrapolation made by its experts” from “what it contends is a statistically valid random sample to prove its claims.” *Id.* at *6.

Robinson, another medical necessity case, involved optometry services provided to Medicare beneficiaries. 2015 WL 1479396, at *1–3. In denying the provider’s motion for summary judgment, the district court rejected arguments that “the necessity of each claim at issue is a subjective determination made by the medical professional on a patient-by-patient basis,” and the “use of samples in order to extrapolate liability” is “improper as a matter of law” because “individualized proof” is required. *Id.* at *5.

Further in *United States ex rel. Martin v. LifeCare*, 114 F. Supp. 3d 549 (E.D. Tenn. 2014), the district court examined the basic principles of statistical sampling in an FCA case alleging lack of medical necessity. The *LifeCare* court examined the extensive case law permitting the use of sampling and concluded that sampling could be used to prove all elements of FCA liability. *Id.* at 565-70. The court observed that “the purpose of statistical sampling is precisely for these types of instances in which the number of claims makes it impracticable to identify and review each claim and statement,” *id.* at 565, and stressed that requiring “claim-by-claim review” in all FCA cases would have the pernicious effect of immunizing the largest

² Medicare covers such services only if a physician certifies that the beneficiary is terminally ill, meaning “the individual has a medical prognosis that his or her life expectancy is 6 months or less.” 42 U.S.C. § 1395x(dd)(3)(A); 42 C.F.R. § 418.3.

perpetrators of fraud, *id.* at 571. “Armed with the knowledge that the government could not possibly pursue each individual false claim,” the court summarized, “large-scale perpetrators of fraud would reap the benefits of such a system.” *Id.* The court concluded that such a result would not be “consistent with the purpose and history of the FCA,” and held that statistical sampling could be used to prove both liability and damages under the FCA, while noting that the defendant would remain free to advance arguments “regarding the inherent limitations associated with statistical sampling” to limit the weight that a “fact finder may accord to the extrapolated evidence.” *Id.* at 571-72.

Other courts have also supported statistical sampling in medical necessity and health care fraud cases. *See also Webb v. Shalala*, 49 F. Supp. 2d 1114, 1122, 1123 (W.D. Ark. 1999) (in medical necessity case, rejecting argument by doctor that sampling deprived him of his “federally protected rights to have each individual case examined . . .[.]” and explaining that “[t]he use of sampling and extrapolation as part of audits to determine overpayments to parties who receive publicly-funded reimbursements has been approved by courts in a number of different settings.”); *Yorktown Med. Lab., Inc. v. Perales*, 948 F.2d 84 (2d Cir. 1991) (statistical sampling appropriate in case involving unnecessary lab tests, among other violations); *Miniet v. Sebelius*, 2012 WL 2930746, at *6 (S.D. Fla. July 18, 2012) (in medical necessity case, propriety of sampling is “undisputed”).

Against this weight of FCA authority, Lincare relies on *United States, et al., ex rel. v. Pfizer, Inc.*, 2016 WL 3017381 (D. Mass. 2016) which is clearly distinguishable on the facts, and on two out-of-Circuit district court decisions which do not support Lincare’s argument that statistical evidence cannot support FCA liability. First, in *Pfizer*, this court based its decision on the fact that relators did not prove the existence of a single false claim. *Id.* at *3. The relators in

that case alleged FCA violations related to Pfizer's promotion of the drug Geodon for certain non-reimbursable indications, resulting in alleged false claims submitted to Medicaid. The court found that the relators had not proven the existence of one false claim; yet the court went on to cite the Ninth Circuit which supported extrapolation - "damages may be extrapolated from aggregate information, but 'submission of a single false claim' [is] necessary." *Id.*, citing *United States v. Kitsap Physicians Serv.*, 314 F.3d 995, 1003 (9th Cir. 2002). Lincare does not argue in this case that relator has not identified a single false claim.

Lincare also relies on *United States ex rel. Wall v. Vista Hospice Care, Inc.*, 2016 WL 3449833 (N.D. Tex. June 20, 2016), which involved challenges to the reliability and admissibility of experts' reports and testimony. The district court decided that statistical evidence was impermissible in the "context" of that case, which involved "an expert's after-the-fact examination of the medical charts of a sample of patients." *Id.* at 13. The court did not hold that such evidence was impermissible in all FCA cases, or even in all FCA cases involving "the clinical picture of individual patients." *Id.* at *12 (distinguishing *Life Care* and *Robinson*); *id.* at *12 n.100 (noting that certain "evidence" may "mak[e] the sample a reasonable basis for extrapolation to the whole"); *id.* at *14 (criticizing the expert's failure to address certain variables but noting that he "could have"). This court need not decide whether statistical sampling is permissible when applied to clinical judgments based on an assessment of detailed medical records, as the present case does not raise that issue.

Lincare also relies on *United States ex rel. Michaels v. Agape Senior Community*, 2015 WL 3903675 (D.S.C. June 25, 2015), which should not be followed here. The district court's analysis of the sampling question was conclusory, equivocal, and secondary to a separate legal question. The primary question in *Agape Senior Community* (currently on appeal in the Fourth

Circuit) was whether the United States was entitled to object to the settlement of a *qui tam* action in which it had not intervened. The district court held that it was, denied the provider's motion to enforce the settlement over the Government's objection, and *sua sponte* certified the question for interlocutory appeal. Then the district court offered an advisory opinion on sampling and extrapolation. It suggested that if its denial of the provider's motion to enforce the settlement was overturned, it would find the Government's objection to the settlement "unreasonable" because it was based on "some form of statistical sampling," which the district court had rejected in a two-paragraph order. *Id.* Instead of providing further detail for this rejection, the district court surveyed cases "on each side of the issue;" found that although "some cases are suited for statistical sampling, this "is not such a case;" and certified that question, too, for interlocutory appeal. *Id.*

Because *Pfizer*, *Vista Hospice Care*, and *Agape Senior Community* are distinguishable and not dispositive here and because statistical evidence is broadly accepted under the FCA, Defendants' argument that Relators cannot use statistical evidence to support FCA liability should be rejected.

CONCLUSION

Based on the foregoing, the United States respectfully requests that this Court deny the Defendants' motion for summary judgment to the extent that it is based on Defendants' misstatements of law related to the use of statistical sampling to support FCA liability.

Respectfully Submitted,

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Dated: December 21, 2016

Certificate of Service

I hereby certify that on this 21st day of December, 2016, the foregoing document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing and paper copies will be sent to those indicated as non-registered participants.

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Assistant U.S. Attorney